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EXAMINER	
LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/417,478	MCCAFFERTY ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Claim Status

1. Claims 1-43 have been canceled.

Claims 44-53 are currently pending;

Claims 44-53 are being examined in this application.

Priority

2. This application appears to be a Divisional of U.S. Patent Application Nos. 08/484,893 (filed 6/07/1995), which is now a US PATENT, 6,172,197, which is a CON of 07/971,857 (filed 1/8/1993; now US PAT 5,969,108), which is a 371 of PCT/GB91/01134 (filed on 7/10/1991).

Drawings

3. The following regarding informal drawings are noted in the previous office action (11/20/2000; pg 2):

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Applicant is invited to notice that boxes 2, 6 and 12 were checked by the draftsman in PTO 948. Applicant is encouraged to amend the specification so that the description of renumbered figure corresponds to the renumbered figures.

Applicant's request of holding the formal drawing requirements in abeyance until allowance is acknowledged.

Claim Rejection(s)/Objection(s) Maintained

Claim Rejections - 35 USC § 112

Second paragraph of 35 U.S.C. 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 44-53 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for the reasons of record as well as necessitated by applicant's amendments to the claims.

Claim 44, in general, is convoluted and confusing. First, it is not clear if the claimed "bacteriophage particles" are structural parts of the "recombinant host cells". The instant claim 44 seems to only recite the intended use of displaying the "member of a specific binding pair" "on the surface of bacteriophage particles" of the claimed "recombinant host cell." However, applicants are asserting the structures of the "bacteriophage particles" provide structural limitations to the claimed "recombinant host cells." (Reply, p.8, para 6).

Second, claim 44 recites "a phagemid genome wherein the only nucleotide sequences derived from filamentous bacteriophage in the phagemid genome are an origin of replication..." which recitation is unclear. The term "genome" is known in the art to represent total genetic material from an organism. However, the instant claim 44 seems to recite that only partial genetic material from an organism is contained within the "genome". This use of the term "genome" appears to contradict the ordinary meaning of the term. Where applicant acts as his or

her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "genome" in claim 44 is used by the claim to mean "partial genetic material of an organism", while the accepted meaning is "total genetic material of an organism." The term is indefinite because the specification does not clearly redefine the term.

Discussion and Answer to Argument

6. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants assert the claim amendments have obviated the previous rejection under 35 USC 112, 2nd paragraph.

However, the claim amendment does not overcome the rejection as discussed above. Applicants are respectively directed to the above rejection for a detailed discussion.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(Note: the instant claim numbers are in bold font.)

Smith et al

8. Claims 44 and 45 are rejected under **35 U.S.C. 102(b)** as being anticipated by Smith et al (Science. Vol. 228: 1315-1317; 6/14/1985; cited in IDS entered 2/1/2000). The previous rejection is maintained for the reasons of record as set forth in the previous Office action.

Discussion and Answer to Argument

9. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue the Smith reference does not "disclose a display of a properly folded functional binding domain". (Reply, p.6+).

Applicants argue that the proteins displayed by the Smith reference do not constitute as "binding domains," because the proteins of the Smith reference are "incomplete and non-functional" and thus do not fall within the definition of a domain. (Reply, p.8, para 2).

Applicants also state that the term "domain" is defined in the instant specification (Reply, p.6, para 2). However, a review of page 15 of the instant specification (as filed on 10/13/1999)

does not reveal a specific definition for the term "domain". In the absence of a clear and explicit definition, the ordinary and customary meaning of the term, "domain" is used. (see MPEP 2111.01). For example, the term "domain" is defined in a bochemistry textbook as "A distinct structural unit of a polypeptide; domains may have separate functions and may fold as independent, compact units" (Lehninger et al., Principles of Biochemistry. 2nd ed., 1993, title page, copy right page and p.G-4 only). Thus, as long as the reference teaches a unit of a polypeptide that is structurally distinct, the reference teaches a "domain" according to the customary and ordinary meaning of the term. Giving the broadest reasonable interpretation of the instant claims in light of the instant specification, the term "domain" can be broadly interpreted to be any fragment of a polypeptide that forms a distinct structural unit.

"During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); In re Prater, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969)."

Applicants also provided a definition from prior art (cited as "Exhibit A"). The definition for the term "domain" cited by applicants is as the followings:

"A domain is a defined as a polypeptide chain or a part of a polypeptide chain that can independently fold into a stable tertiary structure." (Reply, p.6, para 2; emphasis added).

The above cited definition is broad and encompasses any full or partial polypeptide chain that can fold independently. Applicants have also made postulations regarding the displayed proteins of the Smith reference (Reply, p.8, para 2), which are found to be not persuasive.

The Smith reference teaches displaying various proteins (full or fragments thereof) on the surface of the phage particles as part of a fusion protein with the phage gIII coat proteins. The

reference teaches that the proteins (Eco RI endonuclease or fragments thereof) are successfully displayed. That is the proteins are properly expressed and folded and formed a separate "domain" from the gIII coat protein, because gIII coat proteins must be properly formed for the fusion proteins to be displayed on the phage particle surface. In addition, the Smith reference also teaches the displayed proteins are recognized by antibodies, which necessarily entails properly displayed proteins. The antibodies of the Smith reference is specific for Eco RI endonuclease (Smith, p.1315, col.2), and the antibodies must recognize the same or similar protein domains in the phage displayed fragments.

Applicants also assert the proteins displayed by the Smith reference only comprise "just two strands of a three strand anti-parallel β-sheet..." (Reply, p.8, para 2), which would not form a functional domain. Even using applicants provided definition of a "domain" (cited supra), the protein structures comprising "two β strands" are considered as "domains". The two β strands together can be considered as a "tertiary structure". Thus, the displayed protein is "a polypeptide chain or a part of a polypeptide chain", is "independently folded", and is folded into a "tertiary structure".

Applicants also seem to argue because the displayed Eco RI endonuclease fragments may not bind DNA, the displayed proteins cannot be considered "binding domains". (Reply, p.8, para 2). Neither the instant specification nor the instant claims specifically define the term "binding domains". That is the instant disclosure does not specifically limit the "binding" to specific interaction and/or binding partners. The displayed proteins of the Smith reference may or may not bind to DNA, but the proteins are shown to be capable of binding to antibodies (Smith, p.1315). That is the displayed proteins of the Smith reference comprise "binding domains".

Applicants also argue the Smith reference does not teach "the genome of bacteriophage" as presently claimed. (Reply, p.8+).

First, the instant claim as written is convoluted and confusing as discussed supra under the 35 USC 112 2nd paragraph rejection. A discussion of the claim language is needed. The instant claim recites the followings:

"Recombinant host cells each of which harbors a nucleic acid fragment encoding one member of a specific binding pair whereby the host cells collectively harbor a library of nucleic acid fragments comprising fragments encoding a genetically diverse population of specific binding pair members, each member of a specific binding pair being expressed as a fusion with a gene III coat protein surface component of a filamentous bacteriophage so that each said member of a specific binding pair comprises a binding domain for its complementary specific binding pair member and is displayed on the surface of bacteriophage particles, and genetic material of each said bacteriophage particle encodes said bacteriophage particle's displayed member of a specific binding pair, said genetic material being a phagemid genome wherein the only nucleotide sequences derived from filamentous bacteriophage in the phagemid genome are an origin of replication and nucleotide sequence encoding a gene III capsid protein encoding said fusion and wherein said genetic material is packaged into particles by a helper phage whereby each particle has a coat partially derived from the helper phage and partly from said fusion."
(emphasis added).

The instant claim 44 seems to recite products of "recombinant host cells" comprising "nucleic acids" that encode for "fusion proteins" formed between "binding pair members" and "gene III coat proteins". It is not clear if the recited "bacteriophage particles" are parts of the claimed "recombinant host cells". The claim language reciting "is displayed on the surface of bacteriophage particles" can be construed as intended use language. The Smith reference has certainly demonstrated that the recombinant cells (the E coli cells) are capable of displaying the fusion proteins on the surface of the phage particles.

The recitation of "said genetic material being a phagemid genome wherein the only nucleotide sequences derived from filamentous bacteriophage..." are construed as part of the intended use language. In response to applicant's argument that the reference does not teach the intended use of "recombinant host cells" with the specific "phagemid genome", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In this case, the claim language can be construed to recite intended use of the claimed "recombinant host cells" with "bacteriophage particles" and/or "phagemids". As discussed above, the Smith reference teaches "recombinant host cells" (i.e. E coli cells) comprising nucleic acids encoding fusion proteins of gIII coat proteins and Eco RI endonuclease, which fusion proteins are capable of being displayed on the surface of phage particles. Thus, the "recombinant host cells" are capable of performing the intended use of phage displaying. The recitation of "phagemid genome" does not appear to provide additional structural limitations to the claimed "recombinant host cells."

Parmley et al

10. Claims 44 and 45 are rejected under **35 U.S.C. 102(b)** as being anticipated by Parmley et al (Gene. Vol. 73: 305-318; 1988; cited in IDS entered 2/1/2000). The previous rejection is maintained for the reasons of record as set forth in the previous Office action.

Discussion and Answer to Argument

11. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants traversed the above rejection with the same argument as the traversal over the Smith reference. Thus, applicants are respectively directed to the discussion under the Smith reference for answer to arguments.

Applicants argue because the Parmley reference teach displaying part of the β-gal protein, the Parmley reference teaches displaying "an incomplete domain" and the displayed protein has "none of the functions of beta-galactosidase." (Reply, p.6, para 3).

The partial β-gal protein of the reference is displayed as part of the fusion protein (with gIII coat protein), which necessitate the β-gal protein (or fragments thereof) to be displayed as a separate protein domain. In order for the fusion proteins to be successfully displayed on the phage, the fusion proteins must be properly expressed and folded into 3-D structures. Thus, the fusion proteins of the Parmley are properly folded regardless what portion of the β-gal proteins are expressed. According to the definition of a "domain" (provided by applicants) cited above, a domain can be "part" of a polypeptide chain and does not have to be the full protein. As long as the protein fragments are properly displayed into a three dimensional structure, the protein fragments are considered as domains.

Applicants also assert "no folding" of the protein would have been required for the protein's binding to its antibodies. However, applicants have not provided any supporting evidence to indicate the said assertion. Applicant's citation of the "Stanfied" reference is

irrelevant, because the "peptides" of the Stanfied reference is free in solution and are not part of fusion proteins. In fact, the Stanfied reference strengthens the idea that the displayed proteins of the Parmley reference are properly folded and forms 3-dimensional structures. As quoted by applicants, the Stanfied reference states "peptides can adopt a range of structures which can be different when in free solution, than when bound to, for example, an antibody, or when forming part of a protein". (Reply, p.6, last para). That is to say peptides or fragments of proteins can form different conformations from when they are part of a protein or bound to an antibody. Regardless which conformations the proteins form, the proteins are "folded" into 3-D structures unless the proteins are under denaturing conditions.

Ladner ('409)

12. Claims 44 and 45 are rejected under **35 U.S.C. 102(e)** as being anticipated by Ladner et al (US 5,223,409; filed 3/1/1991; priority date: 9/2/1988; cited in IDS filed 2/1/2001). (It is regrettably noted that this rejection was inadvertently set forth under 35 USC 102(**b**) in the previous Office action. This rejection over the Ladner reference was intended to be under 35 USC 102 (e).) The rejection over Ladner et al under 35 USC 102(e) is maintained for reasons of record.

Discussion and Answer to Argument

13. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants traversed the above rejection with the same argument as the traversal over the Smith reference. Thus, applicants are respectively directed to the discussion under the Smith reference for answer to arguments.

Applicants mainly argue that the Ladner reference does not teach the specific "phagemid" as recited in the instant claim 44. (Reply. pp. 9+).

As discussed above, the instant claim 44 seems to recite products of "recombinant host cells" comprising "nucleic acids" that encode for "fusion proteins" formed between "binding pair members" and "gene III coat proteins". It is not clear if the recited "bacteriophage particles" are parts of the claimed "recombinant host cells". The claim language reciting "is displayed on the surface of bacteriophage particles" can be construed as intended use language. The Ladner reference has certainly demonstrated that the recombinant cells (the E coli cells) are capable of displaying the fusion proteins on the surface of the phage particles.

The recitation of "said genetic material being a phagemid genome wherein the only nucleotide sequences derived from filamentous bacteriophage..." are construed as part of the intended use language. In response to applicant's argument that the reference does not teach the intended use of "recombinant host cells" with the specific "phagemid genome", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from

the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In this case, the claim language can be construed to recite intended use of the claimed "recombinant host cells" with "bacteriophage particles" and/or "phagemids". The Ladner reference teaches "recombinant host cells" (i.e. E coli cells) comprising nucleic acids encoding fusion proteins of gIII coat proteins and antibodies (or fragments thereof), which fusion proteins are capable of being displayed on the surface of phage particles. Thus, the "recombinant host cells" are capable of performing the intended use of phage displaying. The recitation of "phagemid genome" does not appear to provide additional structural limitations to the claimed "recombinant host cells."

Applicants also pointed to the discussion of non preferred embodiments of the Ladner reference to indicate that Ladner does not teach the recited phagemid. (Reply. pp.9+)

A non-preferred embodiment of the prior art's teaching constitute as prior art. See MPEP 2123 II.

"Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, .440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994)"

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Parmley et al and Ladner (WO)

15. Claims 44-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parmley et al (Gene. Vol. 73: 305-318; 1988; cited in IDS entered 2/1/2000), in view of Ladner et al (WO 88/06630; 9/7/1988; cited in IDS entered 2/1/2000). The previous rejection is maintained for the reasons of record as set forth in the previous Office action. (It is regrettably noted that "claims 8-20" were inadvertently indicated as rejected in the preamble of the instant rejection in the previous Office action, mailed 5/17/07. Claims 44-53 were pending and were rejected as indicated in the body of the instant rejection in the previous Office action, mailed 5/17/07.)

Discussion and Answer to Argument

16. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue "substitution of a filamentous phage as presently claimed, for a lambda phage would not... have been obvious to one of ordinary skill in the art". (Reply. pp. 12+).

However, the previous Office action discusses the obviousness of using filamentous phage to display antibody fragments, not replacing filamentous phage with lambda phage. The prior art teach displaying various polypeptides using different phages. The prior art (e.g. Parmley) teaches displaying proteins using filamentous phage, and the prior art also teaches using phage (e.g. lambda phage) to display antibody fragments (i.e. types of proteins). Thus, it would have been obvious to a person of ordinary skill in the art to try using the filamentous phage to display antibodies in an attempt to provide an improved antibody displaying on phage particles, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Applicants are respectively directed to the Supreme Court decision:

"The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR, 127 S.Ct. at 1741, 82 USPQ2d at 1396.*

Applicants have not provided any evidence to indicate that using filamentous phage to display antibodies fragments would be inoperative. Thus, the above said rejection is maintained for the reasons of the record as well as the discussion above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1639
11/30/07

/Jon D. Epperson/
Primary Examiner, AU 1639